

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

1(original). An assay method for the detection of potential for CVD or propensity to CVD in a human or non-human animal subject, said method comprising assessing the concentration of calprotectin in a calprotectin-containing sample taken from said subject.

2(original). A method as claimed in claim 1 wherein said sample is a body fluid selected from blood, serum, plasma, urine, cerebrospinal fluid, oral fluid, synovial fluid or empyema fluid.

3(currently amended). A method as claimed in claim 1 ~~or claim 2~~ wherein said sample is blood.

4(currently amended). A method as claimed in ~~any one of claims 1 to 3~~ claim 1 wherein said sample is serum or plasma.

5(currently amended). A method as claimed in claim 3 ~~or claim 4~~ wherein a threshold calprotectin concentration above which said assay is indicative of potential for CVD or propensity to CVD is 0.45 mg/L.

6(currently amended). A method as claimed in ~~any one of claims 1 to 5~~ claim 1 additionally comprising assessing the concentration of a second marker for CVD in said sample.

7(original). A method as claimed in claim 6 wherein said second marker is C-reactive protein.

8(currently amended). A method as claimed in ~~any one of claims 1 to 7~~ claim 1 wherein said CVD is acute myocardial infarction.

9(currently amended). A method as claimed in ~~any one of claims 1 to 8~~ claim 1 wherein said concentration of calprotectin is assessed by turbidimetry.

10(currently amended). An assay kit for use in a method according to ~~any one of claims 1 to 9~~ claim 1, said kit comprising reagents and instructions for the performance of the assay method and for the interpretation of the results.

11(original). A kit as claimed in claim 10 further comprising salprotectin-containing reference samples.

12(currently amended). A kit as claimed in claim 10 ~~or claim 11~~ further comprising a detector.

13(currently amended). A kit as claimed in ~~any one of claims 10 to 12~~ claim 10 further comprising C-reactive protein-containing reference samples.

14(original). An assay method for the determination of calprotectin in a calprotectin-containing body fluid, said method comprising the steps of:

(a) obtaining a calprotectin-containing liquid sample of, or derived from, said fluid;
(b) contacting said sample of said body fluid with a nanoparticle-bound anti-calprotectin antibody or antibody fragment, to bind said calprotectin; and

(c) assessing the calprotectin content by turbidimetry,

wherein the diameter of the antibody or antibody fragment coated nanoparticles is in the range 65-140 nm.

15(original). A method as claimed in claim 14 wherein the diameter of the antibody or antibody fragment coated nanoparticles is in the range 75-120 nm.

16(currently amended). A method as claimed in claim 14 ~~or claim 15~~ wherein said nanoparticles are substantially all of the same size (e.g. monodisperse).

17(currently amended). A method as claimed in ~~any one of claims 14 to 16~~ claim 14 wherein an opacity enhancer is added in between steps (b) and (c).

18(currently amended). A method as claimed in ~~any one of claims 14 to 17~~ claim 14 wherein said body fluid is selected from blood, serum, plasma, urine, cerebrospinal fluid, oral fluid, synovial fluid or empyema fluid.

19(currently amended). A method as claimed in ~~any one of claims 14 to 18~~ claim 14 performed as an automated assay.

20(currently amended). A kit for use as a diagnostic assay according to ~~any one of claims 14 to 18~~ claim 14 comprising:

one or more anti-calprotectin antibodies or antibody fragments immobilised on nanoparticles.

21(original). A kit as claimed in claim 20 further comprising a calprotectin solution of known concentration or a set of such solutions having a range of calprotectin concentrations.

22(currently amended). A kit as claimed in claim 20 ~~or claim 21~~ further comprising a light transmitting vessel.

23(currently amended). A kit as claimed in ~~any one of claims 20 to 22~~ claim 20 further comprising an opacification enhancer.

24(currently amended). A kit as claimed in ~~any one of claims 20 to 23~~ claim 20 further comprising a detector.

25(original). An automated apparatus to receive a calprotectin-containing body fluid sample, apply the anti-calprotectin antibody or antibody fragment immobilised on nanoparticles, optionally apply an opacification enhancer, and assess calprotectin content.

26(currently amended). A method of diagnosis of a disease comprising the method as claimed in ~~any one of claims 14 to 19~~ claim 14 followed by comparison of said calprotectin content with a predetermined threshold value wherein said disease is selected from rheumatic diseases, Sjøgrens syndrome, intraocular inflammatory conditions, cystic fibrosis, acute and chronic lung disease, lung carcinoma, pulmonary cancers, colorectal cancer, inflammatory bowel disease, gastric cancer, colorectal adenoma or cancer, Crohn's disease, ulcerative colitis, gastrointestinal mucosal inflammation, urinary stones, alcoholic liver disease, oral inflammatory mucosal disease, CNS inflammatory disease, HIV infection, secondary CNS infections in HIV infected patients, urinary tract infections, cystitis, pyelonephritis, endogenous posterior uveitis, haematological conditions, febrile conditions (infectious and non-infectious), CVD, acute myocardial infarction and apheresis.

27(original). A method of diagnosis as claimed in claim 26 wherein said disease is CVD.